IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

VEIN & WELLNESS GROUP, LLC, *Plaintiff,* v. XAVIER BECERRA, in his official capacity as Secretary of the United States Department of Health and Human Services, *Defendant.*	Case No. 1:22-cv-00397-JMC

PLAINTIFF'S MEMORANDUM OF POINTS AND AUTHORITIES IN OPPOSITION TO DEFENDANT'S MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF PLAINTIFF'S CROSS-MOTION FOR SUMMARY JUDGMENT

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Pursuant to Federal Rule of Civil Procedure 56, Plaintiff Vein & Wellness Group, LLC ("VWG"), by and through undersigned counsel, respectfully opposes the Motion for Summary Judgment ("Motion") of Defendant Xavier Becerra, in his official capacity as Secretary of the United States Department of Health and Human Services ("Defendant" or the "Secretary"), and moves for summary judgment.

I. Introduction and Summary of Argument

The Secretary's denial of the claims in this Medicare appeal is based on a violation of the Secretary's own regulations. In particular, the Qualified Independent Contractor ("QIC") rejected the claims at issue on the grounds that the wrong billing code was used and, on that basis, VWG appealed. The Secretary's regulations precluded the Secretary from raising "new issues" to deny VWG's claims which is exactly what the Administrative Law Jude ("ALJ") did (for some claims) and what the Medicare Appeals Council ("MAC") did for all the claims. Thus, the ALJ and MAC decisions denying the claims are based on a violation of the Secretary's own regulations and the decision should be reversed.

In addition, the Secretary is barred by mutual collateral estoppel from denying that the claims at issue in this case are covered. On multiple occasions, VWG previously litigated the issue of whether the underlying treatment ("MOCA") is a Medicare-covered benefit/the correct billing codes were used. VWG was victorious in those cases which the Secretary did not appeal. Accordingly, the Secretary is barred by mutual collateral estoppel from denying coverage in this case.

The Secretary's motion for summary judgment seeks to litigate the merits of the MOCA procedure. While the MOCA procedure is appropriate for the claims at issue and VWG could make that showing, doing so would be improper for two reasons: 1) it would be in violation of the Secretary's own regulations regarding "new issues" and evidence; and 2) there is no need for the

Court to engage in that inquiry and VWG declines to re-litigate the matter. Among the purposes of the doctrine of collateral estoppel are to avoid the expenses and burden on both the parties and the Court of repeatedly litigating issues previously decided and to avoid inconsistent results.

Summary judgment in favor of VWG should be granted and the Secretary's motion denied.

II. Background

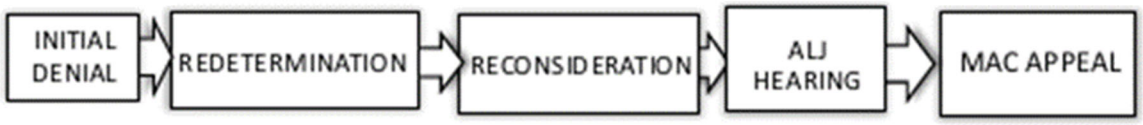
A. The MOCA Procedure

Mechanochemical ablation or MOCA is a procedure used to address the failure of a vein to properly return blood to the heart, particularly, the failure of a vein to resist the pull of gravity and return blood from the lower limbs. When this occurs, blood pools in the legs (rather than returning to the heart) and other veins may be subjected to increased pressure. Increased pressure in the veins can lead to their enlargement, which can cause pain. In addition, there is an increased risk of blood clots developing.

In a MOCA procedure, a catheter is inserted into the problem vein. A wire within the catheter then rotates, inducing a spasm in the vein wall, and a chemical solution is simultaneously injected. This closes off the vein so that blood does not flow through it. As a result, the blood is directed to other, properly functioning, veins and pain is reduced as is the risk of blood clots.

The MOCA procedure is conducted using local anesthesia on an out-patient basis.

B. The Medicare Appeal Process



Because it relates to both issues in this case, some review of the Medicare appeals process will assist the Court.

Claims submitted in Medicare are subject to a five-level appeal process that typically takes more than a year. At issue at each stage of the process is whether the claim is a Medicare covered

benefit/is medically reasonable and necessary. The insured (and/or his provider/supplier) begins by submitting a claim. *See* 42 C.F.R. §§ 405.920-928. If that is denied, "redetermination" can be requested. *See* 42 C.F.R. §§ 405.940-958. If the claim is still denied, "reconsideration" can be requested. *See* 42 C.F.R. §§ 405.960-978. If the claim is still denied, the insured (and/or his provider/supplier) can request a hearing before an ALJ.

Importantly, absent special steps, the ALJ may not consider any and every issue. Instead, the issues the ALJ may consider are limited to those not decided entirely in the insured's favor below and specified in the request for ALJ hearing. *See* 42 C.F.R. § 405.1032(a). New issues may only be considered with notice to the parties prior to the start of the hearing. *See* 42 C.F.R. § 405.1032(b). The effect of this restriction is to prevent sandbagging of the insured or provider by switching bases for denial on appeal.

Indeed, one aspect of the restriction on considering new issues at the ALJ stage is the limitation on submitting/consideration of evidence not presented to the QIC. *See* 42 C.F.R. § 405.1018. Absent approval/explanation, new evidence may not be considered at the ALJ stage. This restriction ties in with the restriction on new issues. Obviously, if new issues were able to be raised at the ALJ stage while new evidence to rebut them was precluded, the parties would be subject to surprise and unable to respond.

The Secretary must provide "hearings" for appeals to the "same extent" as is provided for in Social Security hearings. *See* 42 U.S.C. § 1395ff(b)(1)(A) (citing 42 U.S.C. § 405(b)). That is, in conducting the hearings, the Secretary is authorized to administer oaths, examine witnesses, and receive evidence.

The Secretary has promulgated regulations concerning the conduct of the "hearing" by ALJs. *See* 42 C.F.R. §§ 405.1000-1058. At a minimum, in cases where the insured is represented

by counsel, the hearings are adversarial. In such cases, the Secretary's representative (in the form of the Centers for Medicare and Medicaid Services (CMS) or a contractor to Medicare) has the opportunity to litigate. *See* 42 C.F.R. §§ 405.1008 & 405.1010.

In that capacity, the Secretary (like the insured) can object to the timing of the hearing (42 C.F.R. § 405.1020), object to issues before the ALJ (42 C.F.R. § 405.1024); object to the assigned ALJ (42 C.F.R. § 405.1026); take discovery (42 C.F.R. § 405.1037); present evidence in the form of documents and witnesses (including through subpoenas), cross-examine witnesses, and present argument (42 C.F.R. § 405.1036).

Regardless of whether the Secretary's representative appears, the insured/provider bears the burden of proving entitlement to benefits. After the hearing, the ALJ issues a written decision, which includes findings of fact, conclusions of law, and reasons for the decision and must be based on the evidence admitted at the hearing. *See* 42 C.F.R. § 405.1046. Absent an appeal within 60 days, the ALJ's decision is binding and represents the final decision of the Secretary. *See* 42 C.F.R. §§ 405.1048(a); 405.1110(a).

Like the insured, if the Secretary is dissatisfied with the ALJ's decision, the Secretary can appeal to the Medicare Appeals Council (MAC).[1] *See* 42 C.F.R. §§ 405.1100-1140. Indeed, regardless of whether the Secretary participates in the hearing, the Secretary can appeal an ALJ's decision on so-called "own motion" review. *See* 42 C.F.R. § 405.1110. Finally, if the beneficiary is dissatisfied with the Council's decision, he or she can seek judicial review. *See* 42 U.S.C. § 1395ff(b)(1)(A) (citing 42 U.S.C. § 405(g)).

[1] This is also known as the Departmental Appeals Board ("DAB").

C. Collateral Estoppel Applies to Medicare Cases

Collateral estoppel applies against the United States the same as any litigant and final judgments of agencies acting in a judicial capacity have the same effect as a judgment of a court. Thus, when the Secretary has a fair opportunity to litigate but loses a coverage case before one of his own ALJs, the Secretary is collaterally estopped from relitigating identical issues in future cases brought by the same party. *See Astoria*, 501 U.S. at 107 ("a losing litigant deserves no rematch after a defeat fairly suffered").

1. Collateral Estoppel Generally

Collateral estoppel is a bedrock common law doctrine that bars re-litigation of a legal or fact issue determined in a prior proceeding. Under the doctrine, "once an issue is actually and necessarily determined by a court of competent jurisdiction, that determination is conclusive in subsequent suits based on a different cause of action involving a party to the prior litigation." *Montana v. U.S.*, 440 U.S. 147, 153-54 (1979).

Collateral estoppel serves the triple purposes of protecting litigants from the burden of relitigating an identical issue, promoting judicial economy by preventing needless litigation, and encouraging reliance on adjudication by preventing inconsistent results. *See Allen v. McCurry*, 449 U.S. 90, 94 (1980); *Parklane Hosiery Co., Inc. v. Shore*, 439 U.S. 322, 326 (1979).

Because of the United States' unique posture as a litigant, the Supreme Court has held that only mutual collateral estoppel applies against the United States. *See U.S. v. Mendoza*, 464 U.S. 154 (1984). Accordingly, only a party to a prior proceeding with the government can assert collateral estoppel against the government. Proceedings giving rise to collateral estoppel include agency proceedings. In *Astoria*, the Supreme Court held:

> We have long favored application of the common-law doctrines of collateral estoppel (as to issues) and res judicata (as to claims) to those determinations of administrative bodies that have attained finality. When an administrative

> agency is acting in a judicial capacity and resolves disputed issues of fact properly before it which the parties have had an adequate opportunity to litigate, the courts have not hesitated to apply res judicata to enforce repose. Such repose is justified on the sound and obvious principle of judicial policy that a losing litigant deserves no rematch after a defeat fairly suffered, in adversarial proceedings, on an issue identical in substance to the one he subsequently seeks to raise. To hold otherwise would, as a general matter, impose unjustifiably upon those who have already shouldered their burdens, and drain the resources of an adjudicatory system with disputes resisting resolution. The principle holds true when a court has resolved an issue, and should do so equally when the issue has been decided by an administrative agency, be it state or federal, which acts in a judicial capacity.

501 U.S. at 107-8 (internal citations omitted). *See also B & B Hardware,* 575 U.S. 148-151 (confirming presumption that administrative decisions are subject to issue preclusion).

2. There Is a Presumption that Collateral Estoppel Applies When an Agency Is Acting in a Judicial Capacity

As set forth in *Astoria*, there is a presumption that common law principles (including collateral estoppel) apply to administrative decisions where an agency is acting in a "judicial capacity." *Astoria*, 501 U.S at 108 ("where a common-law principle is well established, as are the rules of preclusion, the courts may take it is as given that Congress has legislated with an expectation that the principle will apply except when a statutory purpose to the contrary is evident."). A party asserting that collateral estoppel does not apply bears the burden of establishing that the presumption has been overcome. *See Green v. Bock Laundry Machine Co.*, 490 U.S. 504, 521 (1989) ("has the burden of showing that the legislature intended such a change.").

To overcome the presumption of the common law, a party must demonstrate that Congress clearly evidenced an intent to do so. *Astoria*, 501 U.S. at 109-110; *U.S. v. Texas*, 507 U.S. at 535 ("an expression of legislative intent to supplant"); *Green*, 490 U.S. at 521 (must show "legislature intended such a change").

Moreover, to overcome the presumption, a statute must "speak directly" to the common law issue. *See Texas*, 507 U.S. at 534. Statutes which are compatible with the pre-existing practice

of the common law do not overcome the presumption. *See BFP v. Resolution Trust Corp.*, 511 U.S. 531, 543 (1994) ("a phrase entirely compatible with pre-existing practice").

Numerous cases have affirmed the application of collateral estoppel based on agency determinations (including against agencies). *See Continental Can Co., U.S.A., v. Marshall*, 603 F.2d 590 (7th Cir. 1979) (DOL collaterally estopped by prior decisions of department); *Bowen v. U.S.*, 570 F.2d 1311, 1321-23 (7th Cir. 1978) (NTSB acting in judicial capacity in prior proceeding, plaintiff collaterally estopped); *Drummond v. Comm'r of Social Security*, 126 F.3d 837, 841-43 (6th Cir. 1997) (SSA collaterally estopped by prior ALJ work determination); *C & N Corp. v. Kane*, 953 F. Supp. 2d 903, 912-14 (E.D. Wisc. 2013) (defendant collaterally estopped by prior TTAB proceeding); *Islam v. U.S. D.H.S.*, 136 F. Supp. 3d 1088 (N.D. Cal. 2015) (D.H.S. collaterally estopped by prior immigration judge's determination). *See also DeWall Enterprises, Inc. v. Thompson*, 206 F. Supp. 2d 992, 1001 (D. Neb. 2002) ("The Secretary's assertions that the ALJ's decisions are not afforded any preclusive effect are without merit.").

Under Fourth Circuit law, the party invoking collateral estoppel has the burden of establishing: 1) the issue or fact is identical to the one previously litigated; 2) the issue or fact was actually resolved in the prior proceeding; 3) the issue of fact was critical and necessary to the judgment in the prior proceeding; 4) the judgment in the prior proceeding is final and valid; and 5) the party to be foreclosed by the prior resolution of the issue or fact had a full and fair opportunity to litigate the issue or fact in the prior proceeding. *See In re: Microsoft Corp. Antitrust Litigation*, 355 F.3d 322, 326 (4th Cir. 2004); Gilbert v. U.S.B.A.T.F., 306 F.Supp.3d 776, 787 (D. Maryland 2018).

Here, the Secretary is indisputably acting in a "judicial capacity" when conducting hearings before his ALJs or the MAC. Thus, collateral estoppel applies to Medicare cases unless the

Secretary can overcome the presumption by identifying statutes evidencing Congress' "clearly expressed" intention to abrogate the common law. That is a burden the Secretary cannot meet and collateral estoppel applies to Medicare cases.

III. Statement of Facts

A. Prior, Final Decisions in VWG's Favor

VWG has litigated the issues of whether the MOCA procedure is a Medicare covered benefit (*i.e.*, is "medically reasonable and necessary"), whether billing code 37241 is the correct code to bill under, and whether coverage is excluded by LCD L32678/34924 multiple times, and been victorious each time.

1. ALJ Appeal No. 3-5707304310

VWG submitted claims for coverage of MOCA procedures under billing code 37241. While those claims were initially paid, the Secretary later recanted and contended that the claims should have not been paid. On further review, the claims were denied on redetermination and on reconsideration on the grounds that the wrong billing code was used and coverage was barred by a Local Coverage Determination (LCD) that applied to sclerotherapy (a different procedure than MOCA). Thereafter, VWG requested an ALJ hearing. At the hearing, VWG was represented by its counsel, Debra Parrish. Subsequently, on July 12, 2021, ALJ Andrea Barraclough issued a decision fully favorable to VWG finding that the LCD L32678 did not apply to the MOCA procedure, that the correct billing code (37241) was used, and ordering coverage. The Secretary did not appeal and the decision became final. *See* Exhibit A.

2. ALJ Appeal No. 3-5712725520

VWG submitted claims for coverage of MOCA procedures under billing code 37241. Those claims were denied initially, on redetermination, and on reconsideration on the grounds that the wrong billing code was used. Thereafter, VWG requested an ALJ hearing. At the hearing,

VWG was represented by its counsel, Debra Parrish. Subsequently, on September 14, 2021, ALJ Andrea Barraclough issued a decision fully favorable to VWG finding that the correct billing codes were used and ordering coverage. The Secretary did not appeal and the decision became final. *See* Exhibit B.

3. ALJ Appeal No 3-5702338364

VWG submitted claims for coverage of MOCA procedures under billing code 37241. Those claims were denied initially, on redetermination, and on reconsideration on the grounds that the wrong billing code was used. Thereafter, VWG requested an ALJ hearing. At the hearing, VWG was represented by its counsel, Debra Parrish. Subsequently, on September 30, 2021, ALJ Andrea Barraclough issued a decision fully favorable to VWG (except as to one claims where documentation was alleged to be missing) finding that LCD L32678/34924 did not apply to the MOCA procedure, that the correct billing code (37241) was used, and ordering coverage. The Secretary did not appeal and the decision became final. *See* Exhibit C.

B. The Claims At Issue In This Case

VWG submitted claims for coverage of MOCA procedures under billing code 37241. The claims were divided into three groups and assigned ALJ Appeal Nos. 3-5712041048, 3-5736021004, and 3-5712041192. While the decisions are not materially different and a single final decision issued by the MAC, VWG presents the underlying decisions separately in order to make the Record cites clear.

In each of the cases, the claims were initially paid. Subsequently, the Secretary changed his mind as part of an audit and denied coverage. The claims were then denied on redetermination and appealed for reconsideration.

1. ALJ Appeal Nos. 3-5712041048

With respect to ALJ Appeal No. 3-5712041048, reconsideration was denied on the grounds that the 37241 was the wrong billing code and that, while LCD L32678/34924 did not explicitly apply, they could still be used to deny coverage, and that documentation was not provided for two of the claims (M.L. on June 2, 2015, and T.G. on June 26, 2014). *See* AR289-96.

VWG sought an ALJ hearing on the grounds that the correct billing code (37241) was used and that the MOCA procedure was not excluded from coverage by LCD L32678/34924. See AR282-84. VWG did not appeal the QIC's denial of two of the claims on grounds of alleged lack of documentation.

After a hearing, at which VWG was represented by counsel, on August 13, 2021, ALJ Lori May issued a partially favorable decision. *See* AR1770-1777. In particular, ALJ May found that the correct billing code (37241) was used. *See* AR1775 ("The records show that the procedure was performed and billed with the appropriate code (37241) in effect on the dates of service at issue."). ALJ May further found that coverage was not barred by LCD L32678/34924. *See* AR1775-76. Thus, while ALJ May found Medicare coverage for all the claims, in relevant part, she excluded coverage for claims based on J.Mi on dates of service of October 7, 2015, and October 14, 2015, on the grounds of alleged lack of documentation. *See* AR1776 ("Medicare coverage for all of the claims at issue, is appropriate and an overpayment did not occur …"). Importantly, alleged lack of documentation to support J.Mi was not a grounds of denial asserted by the QIC or a basis on which VWG sought an ALJ hearing.

2. ALJ Appeal No. 3-5736021004

With respect to ALJ Appeal No. 3-5736021004, reconsideration was denied on the grounds that the 37241 was the wrong billing code and that, while LCD L32678/34924 did not explicitly apply, they could still be used to deny coverage. *See* AR3735-3743.

VWG sought an ALJ hearing on the grounds that the correct billing code (37241) was used and that the MOCA procedure was not excluded from coverage by LCD L32678/34924. See AR282-84.

After a hearing, at which VWG was represented by counsel, on August 13, 2021, ALJ Lori May issued a partially favorable decision. *See* AR3440-3446. In particular, ALJ May found that the correct billing code (37241) was used. *See* AR3444 ("The records show that the procedure was performed and billed with the appropriate code (37241) in effect on the dates of service at issue."). ALJ May further found that coverage was not barred by LCD L32678/34924. *See* AR3445. Thus, while ALJ May found Medicare coverage for all the claims, in relevant part, she excluded coverage for a claim based on E.C. on date of service of February 6, 2014, on the grounds of alleged lack of documentation. *See* AR3446 ("Medicare coverage for all of the claims at issue, is appropriate and an overpayment did not occur …"). Importantly, alleged lack of documentation to support E.C. was not a grounds of denial asserted by the QIC or a basis on which VWG sought an ALJ hearing.

3. ALJ Appeal No. 3-5712041192

With respect to ALJ Appeal No. 3-5712041192, reconsideration was denied on the grounds that the 37241 was the wrong billing code and that, while LCD L32678/34924 did not explicitly apply, they could still be used to deny coverage, and that documentation was not provided for one of the claims (Z.B. on September 9, 2015). *See* AR2194-2205.

VWG sought an ALJ hearing on the grounds that the correct billing code (37241) was used and that the MOCA procedure was not excluded from coverage by LCD L32678/34924. *See* AR2156-59. VWG did not appeal the QIC's denial of the one claim on grounds of alleged lack of documentation.

After a hearing, at which VWG was represented by counsel, on August 13, 2021, ALJ Lori May issued a partially favorable decision. *See* AR1811-1818. In particular, ALJ May found that the correct billing code (37241) was used. *See* AR1816 ("The records show that the procedure was performed and billed with the appropriate code (37241) in effect on the dates of service at issue."). ALJ May further found that coverage was not barred by LCD L32678/34924. *See* AR1816. Thus, while ALJ May found Medicare coverage for all the claims, in relevant part, she excluded coverage for claims based on A.R. on date of service of July 24,2014, on the grounds of alleged lack of documentation. *See* AR1817 ("Medicare coverage for all of the claims at issue, is appropriate and an overpayment did not occur …"). Importantly, alleged lack of documentation to support A.R. was not a grounds of denial asserted by the QIC or a basis on which VWG sought an ALJ hearing.

4. CMS' Referral for "Own Motion Review" and the MAC Decision

CMS appealed ALJ May's decision using a procedure called "own motion review." 42 C.F.R. § 405.1110. *See* AR23-40. There, CMS abandoned the grounds of rejection relied upon by the QIC that was the subject of VWG's request for an ALJ hearing (*i.e.*, that the wrong billing code was used and that LCD L32678//34924). Instead, CMS now argued that the ALJ should have considered "medical reasonableness and necessity" generally. *See* AR38-40.

In its decision, the MAC reversed the ALJ's determinations of coverage (but affirmed the individual cases where the ALJ alleged a lack of documentation). Again, the MAC abandoned the grounds for rejection relied upon by the QIC that were the subject of VWG's request for an ALJ

hearing. Instead, the MAC now denied all the claims on the grounds that MOCA is allegedly not "medically reasonable and necessary." *See* AR14-22. Because general "medical reasonable and necessity" was not a basis for rejection by the QIC and was not an issue before the ALJ, VWG had no notice that that issue would be in play and VWG did not submit the evidence it has that could have addressed the matter. Switching the bases for denial of the claims, the MAC pointed to the lack of evidence as the basis for its decision. *See* AR17 ("… the records do not include any published authoritative evidence, or support any general acceptance by the medical community …"). Most relevant to the issues in this case, the MAC then held: "We find that the MOCA procedure that the appellant furnished to the beneficiaries on the various dates of service at issue in these cases were not medically reasonable and necessary, and, therefore, not covered by Medicare Part B." *See* AR19.

This appeal followed.

IV. Response to the Secretary's Statement of Facts

Pages 8-14 of the Secretary's motion consist of a series of alleged facts regarding the procedure below and MOCA. VWG has recounted what it believes are the relevant procedure facts above and does not believe that a fact-by-fact rebuttal is necessary. With regard to the Secretary's alleged facts regarding MOCA, because the alleged scientific merit of MOCA was not a basis on which either the QIC or the ALJ founded their decisions, as explained below, consideration of that issue is improper.

V. Standard of Review

As described in 42 U.S.C. § 405(g), for issues of fact, the Secretary's conclusion should be upheld if it is supported by substantial evidence. For all other issues (e.g., issue of law,), this Court should apply any standard available under the Administrative Procedure Act ("APA"), including the arbitrary and capricious standard.

VI. Argument

Summary judgment should be granted in VWG's favor because the MAC's denial is based on a violation of the Secretary's own regulations. In addition, summary judgment should be granted in VWG's favor because the Secretary is estopped from contending that the claims at issue are not covered. The Secretary's motion for summary judgment should be denied for the same reasons.

A. The Secretary Violated His Own Regulations In Rejecting VWG's Claims

As detailed above, pursuant to the 42 C.F.R. §§ 405.1032 and 405.1018, the issues and evidence the ALJ may consider are limited. Thus, it is critical that the insured/provider have notice of any bases for denial so that, prior to the QIC decision, the insured/provider can submit any relevant evidence. This is so because the issues and evidence before the ALJ are limited.

In the present case, at all stages through the QIC decision, the only bases for denial allege were that the wrong billing code was used (37241) and that LCD L32678//34924 barred coverage. No other bases were alleged and VWG responded to/addressed those bases accordingly. Given that those were the only bases, VWG's request for an ALJ hearing was limited to those issues. VWG was never provided any pre-hearing notice that any other issue and bases for denial was alleged (*i.e.*, "new issues").

Thus, for example, VWG was never provided with notice that the issue of whether the MOCA procedure was generally (*i.e.*, scientifically) "medically reasonable and necessary" was a basis for denial. Indeed, had VWG been provided with the notice required by the Secretary's own regulations, VWG could have supplied evidence in support of the MOCA procedure. Likewise, VWG was not provided with notice that alleged lack of documentation for J.Mi, E.C., or A.R., was an alleged basis for denial. Had VWG been provided with the pre-hearing notice required by the

Secretary's regulations, VWG could have addressed the issue and pointed the ALJ to the allegedly missing documentation. Because VWG was not provided with that notice, VWG did not do so.

In the present case, the ALJ correctly reversed the denial based on the allegation that billing code 37241 was the wrong code and that LCD L32678//34924 barred coverage. Those were issues on which VWH had proper notice. However, the ALJ violated the Secretary's own regulations when the ALJ denied coverage of the claims related to J.Mi, E.C., and A.R. Again, alleged lack of documentation for the J.Mi, E.C., and A.R. claims was not a basis on which the QIC founded its rejection and not an issue VWG had notice of.

In CMS' referral for "own motion review", CMS alleged that the ALJ erred by not considering "medical necessity and reasonableness" on bases other than the alleged wrong billing code or LCD L32678//34924. Again, pursuant to the Secretary's own regulations (42 C.F.R. §§ 405.1032 and 405.1018), the ALJ could not have erred in that way because that was not an issue on which notice was provided or the subject of VWG's request for an ALJ hearing.

Likewise, when the MAC based its denial on grounds other than the alleged wrong billing code or LCD L32678//34924, the MAC did so in violation of those same regulations and/or the MAC erred when it concluded the ALJ decision was wrong because he did not violate the regulations regarding "new issues"/evidence.

In short, the regulations preclude the sandbagging of the insured/provider that happened here. Claims are submitted and after a full litigation of them, new bases for rejection are created that VWG could have addressed had it had proper notice. In this case, the sandbagging of VWG resulted in the denial of more than $900,000 in claims. That is improper and not in accordance with applicable law and procedures.

Thus, because both the ALJ's decision (in part) and the MAC's decision (in total) is founded on a violation of the Secretary's own regulations, the Secretary violated 5 U.S.C. §§ 706(2)(A) (not in accordance with the law) and 706(2)(D) (without observance of procedure required by law). Accordingly, the decisions at issue should be reversed and coverage of all the claims at issue ordered.

B. The Secretary Is Barred From Denying Coverage By Collateral Estoppel

As detailed above and below, after a full litigation on the merits in multiple instances, VWG received favorable decisions finding that the MOCA procedure is properly billed under code 37241, that MOCA is a covered benefit (and, therefore, is "medically reasonable and necessary"), and is not barred by LCD L32678//34924. The Secretary did not appeal those decisions and they are now final. Subsequently, the MAC in this case found just the opposite. Avoiding the burden of repeated litigation on the parties and the judiciary as well as inconsistent results are the very purposes of collateral estoppel and collateral estoppel should be applied here.

1. Collateral Estoppel Applies to Medicare Cases

As detailed above, collateral estoppel may be based on an agency decision when an agency is acting in a judicial capacity. *See Astoria*, 501 U.S. at 107-8. Further, the United States is bound by mutual collateral estoppel, the same as any other party. *See Mendoza*, 464 U.S. at 163-64.

To the extent that the Secretary alleges that collateral estoppel does not apply to Medicare cases, the Secretary bears the burden of overcoming the presumption that the common law doctrine of collateral estoppel does not apply. *Green*, 490 U.S. at 521. To overcome the presumption, the Secretary must demonstrate that Congress intended to abrogate the common law of collateral estoppel through statutes passed by Congress. *Astoria*, 501 U.S. at 109-110; *Texas*, 507 U.S. at 535. *Green*, 490 U.S. at 521.

Moreover, to overcome the presumption of the common law, a statute must "speak directly" to the common law issue and statutes which are compatible with the pre-existing practice of the common law do not overcome the presumption. *Texas*, 507 U.S. at 534; *BFP*, 531 U.S. at 543.

In the present case, the Secretary cannot sustain his burden of overcoming the presumption that the common law of collateral estoppel applies in Medicare cases.

2. Collateral Estoppel Applies in this Case

There is no genuine issue of material fact that all the elements prescribed for the application of collateral estoppel in *In re: Microsoft* are present in this case and the Secretary is collaterally estopped from denying coverage. The purposes of collateral estoppel in avoiding the burden of re-litigation on VWG, the burden on the judiciary (including before the Secretary), and the prosect of inconsistent results are served by applying collateral estoppel in this case. *Allen*, 449 U.S. at 94; *Parklane*, 439 U.S. at 326.

a) The Issue Or Fact Is Identical To the One Previously Litigated

At issue in every Medicare case is whether the claim or service is a Medicare covered benefit. Pursuant to the statutes, only items that are "medically reasonable and necessary" are covered by Medicare. *See* 42 U.S.C. § 1395y(a)(1)(A). Thus, anytime is it decided that a claim is covered, it has necessarily been determined that the service/item is medically reasonable and necessary.

As shown in Exhibits A, B, and C, the MOCA procedure was determined to be a Medicare covered benefit (and, therefore, "medically reasonable and necessary") in the prior decisions. *See, e.g.,* Exhibit A at 7 ("[The MOCA procedure] billed by Appellant under CPT code 37241 for the dates of service are covered and payable by Medicare."); Exhibit B at 8 (same); Exhibit C at 14 ("Medicare coverage applies as it was appropriate for the physician's services to be billed by

Appellant under CPT code 37241. … Medicare shall pay Appellant for all the previously uncovered services outlined in Conclusion No. 1.").

In this case, the MAC's denial states: "We find that the MOCA procedure that the appellant furnished to the beneficiaries on the various dates of service at issue in these cases were not medically reasonable and necessary, and, therefore, not covered by Medicare Part B." *See* AR19. Thus, the issue/fact of coverage (including "medical reasonableness and necessity") in this case is identical to the same issue/fact in the prior decisions.

Accordingly, the issue or fact in this case is identical to the one previously litigated.

b) The Issue or Fact Was Actually Resolved in the Prior Proceeding

As detailed above, the issue or fact as to whether the MOCA procedure is a Medicare covered benefit (and, therefore, whether it is "medically reasonable and necessary", was actually resolved in each of the prior decisions. Each decision ordering coverage resolved this issue(s).

c) The Issue or Fact Was Critical and Necessary to the Judgment in the Prior Proceeding

Obviously, given that Medicare coverage of the MOCA procedure was the very thing being disputed and sought in the prior proceedings, a determination that the MOCA procedure is a Medicare covered benefit was critical and necessary to the judgment. Likewise, because coverage is dependent on a service/device being "medically reasonable and necessary" (42 U.S.C. § 1395y(a)(1)(A)), resolution of that fact/issue in VWG's favor was a critical and necessary to the judgment in the prior decisions.

d) The Judgment in the Prior Proceeding Is Final and Valid

As detailed above, absent an appeal within 60 days, the ALJ's decision is binding and represents the final decision of the Secretary. *See* 42 C.F.R. §§ 405.1048(a); 405.1110(a). In the present case, the Secretary did not appeal any of the prior ALJ decisions within 60 days.

Accordingly, each decision became final and there is no basis for challenging the validity of those decisions.

e) The Secretary Had a Full and Fair Opportunity to Litigate in the Prior Proceedings

As detailed above, VWG was represented in each of the prior ALJ decisions. As a result, there is no genuine issue of material fact that the Secretary had a full and fair opportunity to litigate in the prior proceedings. As detailed above, under the Secretary's own regulations, when an insured/provider is represented (as VWG was in this case), the Secretary has all the rights of a litigant (including the right to call witnesses, cross-examine, etc.). Thus, the Secretary had a full and fair opportunity to litigate in the prior proceedings. There is no genuine issue of material fact that the Secretary had a "full and fair opportunity: to litigate" in the prior proceedings.

Thus, because the Secretary is collaterally estopped from denying coverage, the Secretary's denial of coverage is not supported by substantial evidence/is arbitrary and capricious and the decisions at issue should be reversed and coverage of all the claims at issue ordered.

C. Response to the Secretary's Motion

VWG will not address every argument raised by the Secretary as VWG does not believe that is necessary to resolve the motions. Essentially, the Secretary seeks to litigate the merits of the MOCA procedure and the ALJ/MAC's new basis for denial of VWG's claims. That is, the Secretary contends that the MAC decision should be affirmed because of the alleged lack of scientific evidence that the MOCA procedure is "medically reasonable and necessary."

As set forth herein, the Secretary's approach is barred by the Secretary's regulations and collateral estoppel and illustrates the sandbagging that the Secretary's own regulations proscribe. It is elemental that the judicial review is based on the administrative record. *See* 42 U.S.C. §

405(g).[2] Thus, whereas here, both the ALJ and the MAC base their denials on "new issues" of which the insured/provider has no notice, the insured/provider is prevented from submitting the very evidence that could rebut. Clearly, that is improper and inconsistent with law.

Indeed, this case aptly illustrates why such an approach is barred. VWG has evidence it could have submitted before the QIC (as well as the ALJ) regarding the scientific merit (*i.e.*, "medical reasonableness and necessity") of the MOCA procedure. However, because no notice was provided to VWG that that was an issue on which coverage was denied, VWG did not submit the evidence it has and is barred from now doing so. Avoiding exactly this situation is why the Secretary's regulations require notice of the issues before the ALJ (so that any relevant evidence can be submitted) and preclude ALJs and the MAC from raising "new issues", without proper notice.

Some of the Secretary's other comments merit a response. The Secretary contends that the Medicare Administrative Contractor (*i.e.*, the first two levels of appeal) and the QIC denied coverage on the grounds that MOCA is not "medically reasonable and necessary." Mot. at 27. With regard to the QIC, the Secretary cites AR3716-3724. Respectfully, that citation actually supports VWG's position. During the proceedings below, VWG pointed out that the Secretary had previously covered the MOCA procedure and submitted a prior QIC decision so finding. That is the document at AR3716-3724, where the QIC determined that the MOCA procedure was covered/medically reasonable and necessary. *See* AR3723 (The decision of the QIC is favorable;

[2] However, because of the context in which it may arise, a Court may properly consider non-record materials as a basis for collateral estoppel.

the services met the requirement to be considered reasonable and necessary for the treatment of the patients.").[3]

With regard to what the Medicare Administrative Contractors, the Secretary's citation is to a reconsideration request form and is not evidence for the Secretary's contention. In any event, it is irrelevant what the Medicare Administrative Contractors said or did not say, as the issues before the ALJ are those that are specified in the request for an ALJ hearing and (as shown above) VWG's request was limited to the bases on which the QIC denied coverage (*i.e.*, allegedly wrong billing code used and LCD L32678/34924).

The Secretary attempts to address the violation of his own regulations regarding "new issues" on pages 31-33. There, the Secretary appears to contend that any issue can be considered by the MAC on the grounds that: 1) MAC review of ALJ decisions is *de novo;* and 2) that the MAC can review any issue that CMS puts in its request for review. These arguments are both without merit.

First, *de novo* review does not mean not subject to the law/regulations. Thus, while the MAC considers the issues the ALJ decided *de novo*, MAC review is still limited to the issues for which there was proper notice. Accordingly, in this case, the MAC could have reviewed *de novo* the ALJ's decision that the proper billing code was used and that the relevant LCDs did not bar coverage. But the MAC could not consider "new issues" and base a denial on them as it did in this case.

[3] The QIC decisions in this case did contend that MOCA was not "medically reasonable and necessary", but did so on the basis that the wrong billing code was used and that coverage was barred by LCD L32678//34924. *See* AR295. No decision by the QIC or the ALJ was based on the allegation that MOCA was not "medically reasonable and necessary" on the grounds that there was a lack of scientific evidence to support MOCA.

Second, with regard to MAC's review, all the relevant regulations provide is that the review is limited to the matters specified in the request for review (*see* 42 C.F.R. § 405.1112(c)). That is, the review may not go beyond what has been requested. At the same time, not everything can be reviewed. Pursuant to 42 C.F.R. § 405.1110(c)(2), where, as here, CMS did not participate below, the review is limited to alleged errors of law or broad policy or procedural issues. Review is further limited by the issues that were properly before the ALJ. Otherwise, 42 C.F.R. § 405.1032, *e.g.*, would be rendered superfluous. Constructions of statutes/regulations which render them superfluous are, of course, disfavored. In the present case, CMS sought MAC review on the grounds that the ALJ made an error of law when he did not violate 42 C.F.R. § 405.1032 and consider a "new issue" without notice to VWG. Limited to that issue, as the MAC was by 42 C.F.R. § 405.1112(c)), the MAC again violated the law when it based its denial on a "new issue" (i.e., whether MOCA is "medically reasonable and necessary."

The Secretary also contends that VWG is not prejudiced by the MAC's denial of the claims on a basis for which no notice was provided (*i.e.*, the alleged lack of scientific evidence of "medical reasonableness and necessity." Mot. at 32. There is no basis for this contention. Given that the QIC's denials were based solely on the alleged wrong billing code and LCD L32678/34924, VWG had no notice to submit evidence on other issues. This is especially true where consideration of "new issues" and evidence is barred by the Secretary's own regulations. Moreover, even at the MAC, consideration of evidence is limited to the evidence that was before the ALJ. *See* 42 C.F.R. 405.1122(a). Having had no notice, VWG was precluded from submitting evidence after the QIC' decision and could not submit evidence for the first time to the MAC. Thus, VWG was prejudiced by the Secretary's failure to follow his own regulations.

Finally, the Secretary closes with the contention that attorney's fees are not available in § 405(g) cases. Mot. at 33. His position is devoid of merit. Pursuant to 28 U.S.C. § 2412 attorney's fees may be awarded to VWG if VWG is victorious and the Secretary fails to prove that his position was "substantially justified" (d) or was in "bad faith" (b). *See Olsen v. Becerra*, 2021 WL 3683360 (E.D. Wash. April 20, 2021) (Secretary's underlying position and litigation conduct constituted "bad faith", attorneys fees awarded).

VII. Conclusion

WHEREFORE, for the reasons set forth above, the Court should deny the Secretary's motion for summary judgment, grant VWG's motion for summary judgment, reverse the Secretary's denials, and find that the Secretary is collaterally estopped from denying coverage of the claims at issue in this case. Pursuant to 42 U.S.C. § 405(g) (fourth sentence), the Court should remand this matter to the Secretary with instructions to cover all the claims at issue.

Dated: June 27, 2022

Respectfully submitted,

/s/Daniel Z. Herbst

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CERTIFICATE OF SERVICE

I hereby certify that on June 27, 2022, a true and correct copy of the Plaintiff's Opposition to Defendant's Motion for Summary Judgment and Plaintiff's Cross Motion for Summary Judgment was filed via the Court's CM/ECF system and served upon all attorneys of record.

/s/Daniel Z. Herbst
Daniel Z. Herbst (Bar No. 17510)